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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,683	06/06/2003	Michael Albert Strobel	101918.56959C1	1628

23911 7590 06/29/2006

CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON, DC 20044-4300

EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,683	STROBEL, MICHAEL ALBERT	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/22/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

Claims 1-18, as filed 6 June 2003, are presented for examination.

The request to correct the priority date to 7/23/2001, and status as a CON of 09/910076 now US Patent No. 6,627,613 has been acknowledged.

Drawings

The drawings filed 22 November 2004 do not appear to belong to the instant application. The do not relate to the claimed subject matter and there is no mention or description of them in the specification.

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the invention as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 16 and 17 are objected to because of the following informalities: the claims contain periods within the claims (which are not abbreviations). It is suggested that "a." be amended to "a)" for example. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1-18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,627,613. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a pharmaceutical solution of ivermectin, without benzyl alcohol, for treatment of infestations caused by parasites, as well as the same method for preparing the formulation.

Claim Rejections - 35 USC § 112, 1st paragraph: New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2) Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains *new* subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 6, and 11 contain the limitations "without benzyl alcohol, N-methylpyrrolidone or 2-pyrrolodone...". Exclusion of the components N-methylpyrrolidone and 2-pyrrolodone is not specifically disclosed in the specification or claims of the current application or in the parent application (09/910076 now US Patent No. 6,627,613). While the parent specification discusses US Patent No. 5,773,422 which uses forms of pyrrolidone solvents N-methylpyrrolidone and 2-pyrrolodone (see

paragraphs [0019] and [0025]), it does not recite the specific exclusion of these components in the claimed composition (e.g. claim 1, with ivermectin, ethyl alcohol, and polysorbate 80).

New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a component of a composition or a step from a method. In other words, a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species.

It is noted that the instant application is a Continuation of said parent application (09/910076 now US Patent No. 6,627,613) and therefore any new matter in the instant application is properly rejected as such. Applicant may, however, overcome this rejection by changing the instant application to a Continuation-in-part application form said parent (09/910076 now US Patent No. 6,627,613).

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2) Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 6, and 11 contain the limitations "without benzyl alcohol, N-methylpyrrolidone or 2-pyrrolodone..." It is unclear if the composition is to be without *one* or *all* of the recited ingredients.

3) Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11, it is not clear how much of the 50% propylene glycol and 50% polysorbate 80 solutions is being added to the result in the claimed solution.

4) Claim 16 recites the limitation "the prolylene glycol" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5) Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,773,422 (Komer).

Komer teaches an ivermectin solution without benzyl alcohol for treatment of a broad spectrum of endo- and ecto-parasites (See: abstract; col. 1, lines 47-49; claims 1-

26). The reference teaches oral, injection, and topical administration (col. 2, lines 15-16). The reference teaches formulations containing water (col. 4, Examples 1, 2, and 4). The reference also teaches inclusion of the surfactant polysorbate 80 (col. 3, last line; Examples 14 and 16-18). The reference also teaches ivermectin in 2-propanol (isopropanol) (col. 1, lines 50-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6) Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,773,422 (Komer) in view of US Patent No. 6,063,394 (Grosse-Bley et al.).

Komer teaches an ivermectin solution without benzyl alcohol for treatment of a broad spectrum of endo- and ecto-parasites (See: abstract; col. 1, lines 47-49; claims 1-26). The reference teaches oral, injection, and topical administration (col. 2, lines 15-16). The reference teaches formulations containing water (col. 4, Examples 1, 2, and 4). The reference also teaches inclusion of the surfactant polysorbate 80 (col. 3, last line; Examples 14 and 16-18). The reference also teaches ivermectin in 2-propanol (isopropanol) (col. 1, lines 50-60). Komer does not teach ethanol as a solvent for ivermectin.

Grosse-Bley et al. teach injection formulations of avermectins, including ivermectin, using ethanol as a co-solvent. (See: abstract; col. 1, lines 6-20; col. 8, lines 5-10).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the instantly claimed ivermectin solution with ethanol (ethyl alcohol). The skilled artisan would have been motivated to use ethanol and would have had a reasonable expectation of success, having been taught by Grosse-Bley et al. that it is known to use ethanol as a co-solvent for ivermectin in a pharmaceutical formulation (i.e. for injection). Therefore, the invention as a whole would have been prima facie obvious.

7) Claims 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,773,422 (Komer).

Komer teaches an ivermectin solution without benzyl alcohol for treatment of a broad spectrum of endo- and ecto-parasites (See: abstract; col. 1, lines 47-49; claims 1-26). The reference teaches that the formulation contains from 0.1% to 40% by weight of the ivermectin (see claims 1 and 2). The reference teaches oral, injection, and topical administration (col. 2, lines 15-16). The reference teaches formulations containing water up to 90% by volume (col. 3, lines 12-14; col. 4, Examples 1, 2, and 4). The reference also teaches ivermectin in 2-propanol (isopropanol) (col. 1, lines 50-60). The reference also teaches inclusion of the co-solvent propylene glycol up to 95% by volume (col. 3,

lines 15-20 and 35-40), and the surfactant polysorbate 80 (col. 3, last line; Examples 14 and 16-18).

While Komer does not teach propylene glycol and polysorbate 80 in 50% solutions, the reference nonetheless teaches inclusion of the components in the ivermectin solution. The broadly described ranges of propylene glycol and polysorbate 80 as taught by Komer would be inclusive of at least small amounts of each generically in many ratios inclusive of 50%/50%. Also see the 35 USC § 112, 2nd paragraph rejection above, which notes that the amount of propylene glycol and polysorbate 80 in the claimed composition could be present in trace amounts up to large amounts of each component, independently, thus including the 50%/50% mixture amounts as instantly claimed.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use 50% solutions of polysorbate 80 and propylene glycol. The skilled artisan would have been motivated to use the 50% solutions and would have had a reasonable expectation of success having been taught by Komer that it is known to include polysorbate 80 and propylene glycol in ivermectin solution for pharmaceutical formulations.

8) Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,773,422 (Komer) in view of US Patent No. 6,063,394 (Grosse-Bley et al.), and further in view of US Patent No. 5,645,856 (Lacy et al.).

Komer is applied as above to claims 1-8 and 10. Komer in view of Grosse-Bley et al. is applied as above to claims 11-13, and 15.

Komer and Grosse-Bley et al. do not teach addition of a sweetener.

Lacy et al. teach oral pharmaceutical formulation for hydrophobic drugs, including ivermectin. The reference teaches the addition of sweeteners, such as aspartame, to the formulations. (See: abstract, col. 1, lines 1-15; col. 10, lines 52-65, col. 13, line 58- col. 14, line 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include sweeteners (such as aspartame) in the instantly claimed ivermectin solution. The skilled artisan would have been motivated to add the sweetener (such as aspartame) to the solution in order to make the solution more palatable for the oral formulation. The person of ordinary skill in the art would have had a reasonable expectation of success in making such a sweetened formulation, having been taught by Lacy et al. that it is known to add such sweeteners to a formulation of hydrophobic drugs like ivermectin for an oral formulation. Therefore, the invention as a whole would have been prima facie obvious.

Conclusion

Claims 1-18 are rejected. No claims are allowed.

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614

Ardin Marschel
SPE
Art Unit 1614

Ardin H. Marschel 6/27/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER